K070346

JUL 18 2007

510(k) Summary

510(k) Submission Information:

Device Manufacturer: Dade Behring Inc.
Contact name: Robert Eusebio, Regulatory Affairs Manager
Fax: 916-374-3144
Date prepared: February 2, 2007
Product Name: Microbiology rule-based software system
Trade Name: Dade Behring LabPro Alert$_{Ex}$ Software System
Intended Use: To notify the user of unusual conditions, or out-of-range results that may warrant further analysis or action and/or to provide the user with the ability to change organism identifications and/or antibiotic susceptibility test interpretations.
510(k) Notification: New microbiology rule-based software system – Dade Behring LabPro Alert$_{Ex}$ Software System
Predicate device: BDXpert System resident on the EpiCenter System (K040099)

510(k) Summary:

The Dade Behring LabPro Alert$_{Ex}$ Software System is a rule-based software application within the LabPro Data Management System Software version 3.0. The initial LabPro software releases (prior to version 3.0) contained Alert functionality that automatically notified the user of unusual conditions or out-of-range results that may warrant further analysis or action. The LabPro Alert$_{Ex}$ software offers added functionality including the ability to change the organism identification (ID) and/or antimicrobial susceptibility testing (AST) interpretations.

The proposed LabPro Alert$_{Ex}$ Software System substantially equivalent to the BDXpert System resident on the EpiCenter System, as defined in the FDA document "Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA", dated February 5, 2003. The Premarket Notification (510[k]) presents the software development and verification and validation testing processes used for the LabPro Alert$_{Ex}$ Software.

The LabPro Alert$_{Ex}$ Software Verification and Validation Testing confirmed that the Alert$_{Ex}$ software operates in accordance with the intended functional requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 18 2007

Mr. Robert Eusebio
Regulatory Affairs Specialist
Dade Behring, Inc.
2040 Enterprise Blvd
West Sacramento, CA 95691

Re: K070346
Trade/Device Name: Dade Behring LabPro Alert$_{Ex}$ Software System
Regulation Number: 21 CFR 866.1645
Regulation Name: Fully Automated Short Term Incubation Cycle Antimicrobial Susceptibility Device
Regulatory Class: Class II
Product Code: LON
Dated: July 9, 2007
Received: July 10, 2007

Dear Mr. Eusebio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240)276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070346

Device Name: *Dade Behring LabPro Alert$_{Ex}$ Software System*

Indications For Use:

The Dade Behring LabPro Alert$_{Ex}$ Software System is intended for use with the LabPro Data Management System Software, version 3.0 and MicroScan® Instruments (e.g., WalkAway *SI*, autoSCAN-4). The Alert$_{Ex}$ Software notifies the user of unusual conditions, or out-of-range results that may warrant further analysis or action, and/or provides the user with the ability to change organism identifications and/or antibiotic susceptibility test interpretations.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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